

## Perspective

## Medical Marijuana and the Law

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The U.S. legal landscape surrounding "medical marijuana" is complex and rapidly changing. Fourteen states — California, Alaska, Oregon, Washington, Maine, Hawaii, Colorado, Nevada,

Vermont, Montana, Rhode Island, New Mexico, Michigan, and most recently, New Jersey - have passed laws eliminating criminal penalties for using marijuana for medical purposes, and at least a dozen others are considering such legislation.1 Medical experts have also taken a fresh look at the evidence regarding the therapeutic use of marijuana,<sup>2,3</sup> and the American Medical Association (AMA) recently adopted a resolution urging review of marijuana as a Schedule I controlled substance, noting it would support rescheduling if doing so would facilitate research and development of cannabinoid-based medicine. Criticizing the patchwork of state laws as inadequate to establish clinical standards for marijuana use, the AMA has joined the Institute of Medicine, the American College of Physicians, and patient advocates in calling for changes in federal drug-enforcement policies to establish evidence-based practices in this area.

States have led the medical marijuana movement largely because federal policymakers have consistently rejected petitions to authorize the prescription of marijuana as a Schedule II controlled substance that has both a risk of abuse and accepted medical uses. Restrictive federal law and, until recently, aggressive federal law enforcement have hamstrung research and medical practice involving marijuana. The federal Controlled Substances Act (CSA) classifies marijuana as a Sched-

ule I drug — one with a high potential for abuse and "no currently accepted medical use" and criminalizes the acts of prescribing, dispensing, and possessing marijuana for any purpose. Although physicians may recommend its use under First Amendment protections of physician-patient communications, as set forth in the 2002 federal appeals court decision Conant v. Walters, they violate federal law if they prescribe or dispense marijuana and may be charged with "aiding and abetting" violation of the federal law if they advise patients about obtaining it. A 2005 Supreme Court decision (Gonzales v. Raich) made clear that regardless of state laws, federal law enforcement has the authority under the CSA to arrest and prosecute physicians who prescribe or dispense marijuana and patients who possess or cultivate it.

Nevertheless, in October 2009, the Department of Justice issued

a memorandum to U.S. Attorneys stating that federal resources should not be used to prosecute persons whose actions comply with their states' laws permitting medical use of marijuana. This change in the Justice Department's prosecutorial stance paved the way for states to implement new medical-marijuana laws, and states are now attempting to design laws that balance concerns about providing access for patients who can benefit from the drug with concerns about its abuse and diversion. Although the current state laws facilitate access, they do little to advance the development of standards that address the potency, quality, purity, dosing, packaging, and labeling of marijuana.

All the state laws allow patients to use and possess small quantities of marijuana for medical purposes without being subject to state criminal penalties. They also allow a patient's "caregiver" - an adult who agrees to assist with a patient's medical use of marijuana - to possess, but not use, marijuana. Most laws protect "qualifying" patients, who are variously defined as those who have received a diagnosis of a debilitating medical condition and have written documentation (or, in one case, an oral recommendation) from their physician indicating that they might or would "benefit from the medical use of marijuana" or that the "potential benefits of medical use of marijuana would likely outweigh the health risks." Definitions of "debilitating medical condition" vary by state (see Table 1) but typically include HIV-AIDS, cachexia, cancer, glaucoma, epilepsy and other seizure disorders, severe nausea, severe and chronic pain, muscle spasms from multiple sclerosis or Crohn's disease,

and other conditions. All but two states allow additions to this list if approved by the state health department.

State laws do not regulate marijuana's quality or potency, and most don't address ways of obtaining the drug. Virtually all permit patients or caregivers to cultivate marijuana. New Jersey's new law prohibits such cultivation but provides for the establishment of alternative treatment centers that will "fill" a physician's written instruction for a certain quantity of marijuana. Most laws are silent on whether patients or their caregivers may buy or sell marijuana or whether dispensaries are permitted (see Table 2). California permits dispensing through cooperatives or collectives, but until recently most other states did not — a situation that is changing with the enactment of some recent laws and amendments.

Most of the statutes also limit the amount of marijuana that patients or caretakers can possess or cultivate, although the quantities allowed are not derived from clinical trials or pegged to a medical condition (see Table 2). The amounts range from 1 oz and 6 plants in Alaska to 24 oz and 15 plants in Washington, an amount that Washington considers to be a "60-day supply." California's original medical-marijuana ballot initiative did not specify an allowed quantity, instead permitting an amount reasonably related to the patient's medical needs. Subsequent legislation set limits, which apply to individuals who register and thereby gain protection from arrest, but the California Supreme Court recently struck down the limits as they apply to unregistered patients who possess amounts of marijuana acceptable under the original ballot initiative. Such patients can be arrested, but if prosecuted can assert that the quantity they possess is reasonably related to their needs. Under the New Jersey law, physicians must provide patients with written instructions specifying the amount of marijuana to be dispensed by legally sanctioned treatment centers, but the maximum amount for a 30-day period is 2 oz - making a "60day supply" in New Jersey just 4 oz, one sixth of that in Washington, a disparity that underscores the absence of standards.

The laws also vary in terms of whether they establish a registry and issue identification cards for qualifying patients. Eleven of the 14 states have a registry, and Maine and New Jersey will soon. In most states where patients have identification cards, they are protected from arrest and prosecution. In some states, however, registered patients with identification cards may be arrested but can use the defense that they have a demonstrated medical need for marijuana. And in a few states, unregistered but "qualifying" patients who meet other requirements of the law may also use this defense.

Missing from many state laws is a requirement that physicians recommending medical marijuana to adult patients provide the rudimentary disclosure of risks and benefits necessary for informed consent, although such disclosure is generally required for patients who are minors. In Canada, the first country to decriminalize medical marijuana, regulations require that physicians discuss the risks with their patients, yet the lack of relevant clinical trials of smoked cannabis makes it difficult for physicians to comply with the law.4

	Table 1	. Diseases a	and Condi	ions for \	vhich M	edical Mar	ijuana Use	e Is Perm	Table 1. Diseases and Conditions for Which Medical Marijuana Use Is Permitted According to State Laws. $st$	to State Lav	vs.*			
Qualifying Diseases and Debilitating Conditions	Alaska	Alaska California Colorado Hawaii	Colorado		Maine N	Michigan	Michigan Montana Nevada	Nevada	New Jersey	New Mexico <del>'</del>	Oregon	Rhode Island	Vermont	Vermont Washington
Cancer	×	×	×	×	×	×	×	×	X (if terminal)	×	×	×	∬‡×	×
Glaucoma	×	×	×	×	×	×	×	×	×	×	×	×		\$X
HIV–AIDS	×	×	×	×	×	×	×	×	×	×	×	×	∬‡×	×
Hepatitis C						×						×		\$×
Alzheimer's disease						×					×	×		
Nail-patella syndrome						×								
Amyotropic lateral sclerosis						×			×					
Cachexia, or wasting syndrome§	×	×	×	×	×	×	×	×	×		×	×	×	ׇ
Severe or chronic pain§	×	×	×	×		×	×	×	×		×	×	×	ׇ
Severe nausea∬	×	×	×	×	×	×	×	×	×		×	×	×	\$X
Seizures§	×	×	×	×	×	×	×	×		X (epilepsy)	×	×	×	×
Intractable spasticity									×					‡x
Anorexia		×												×
Severe muscle spasms	×	×	×	×	×	×	×	×			×	×		¢x
Multiple sclerosis									×	×			×	×
Spinal cord damage, with neurologic indication of muscular spasticity										×				
Appetite loss					×									×
Cramping														×
Arthritis		×												
Migraine		×												
Muscular dystrophy									×					
Inflammatory bowel or Crohn's disease	0					×			×					×
Admission to hospice care or terminal illness									×	×				
Any other chronic or persistent medical condition		×*X												
Any other medical condition approved by state agency	×		×	×	×	×	×	×	×	×	×	×		×
<ul> <li><sup>*</sup> Data are from the National Alliance for Model State Drug Laws and relevant state statutes and regulations. MS denotes multiple sclerosis.</li> <li><sup>†</sup> Since the passage of New Mexico's medical-marijuana law, the state Department of Health has approved nine new conditions.</li> <li><sup>†</sup> Medical marijuana can be used for these conditions if they are resistant to conventional medical therapy.</li> <li><sup>†</sup> In these instances, the use of marijuana generally must be associated with a chronic, debilitating disease or its treatment.</li> <li><sup>†</sup> Medical marijuana can be used to treat these symptoms when resulting from AIDS or AIDS treatment or from cancer or its treatment.</li> <li><sup>†</sup> Medical marijuana can be used if a physician has determined that a patient has less than 12 months to live.</li> <li><sup>**</sup> Medical marijuana can be used if the condition substantially limits the ability of the patient to conduct one or more major life activities as defined by the Americans with Disabilities Act of 1990 or, if the condition is not alleviated, may compromise the patient's safety or cause serious harm to the patient's physical or mental health.</li> </ul>	for Mod medical- these con lana gen reat thes physiciar thesiciar thesiciar	el State Dr marijuana nditions if t erally musi e symptom n has deter n substant ed, may co	ug Laws a law, the s <sup>-</sup> law, the s <sup>-</sup> hey are re hey are sesoc : be assoc : be assoc s when re mined tha mined tha ially limits ially limits	nd releva ate Depa sistant to ated with sulting fri the abilit the abilit	nt state : rtment c convent a chron om AIDS m AIDS it has les t has les y of the p	statutes ar of Health h tional med ic, debilita ic, or AIDS t i or AIDS t s than 12 s than 12 s than 12 s than 2 s than 3 s than	te Drug Laws and relevant state statutes and regulations. I uana law, the state Department of Health has approved ni us if they are resistant to conventional medical therapy. must be associated with a chronic, debilitating disease or ptoms when resulting from AIDS or AIDS treatment or fro determined that a patient has less than 12 months to live. ostantially limits the ability of the patient to conduct one or r ay compromise the patient's safety or cause serious harm	ons. MS ed nine r yy. se or its 1 or from c live. e or mor harm to t	te Drug Laws and relevant state statutes and regulations. MS denotes multiple sclerosis uana law, the state Department of Health has approved nine new conditions. must per associated with a chronic, debilitating disease or its treatment. ptoms when resulting from AIDS or AIDS treatment or from cancer or its treatment. determined that a patient has less than 12 months to live. stantially limits the ability of the patient to conduct one or more major life activities as def asy compromise the patient's safety or cause serious harm to the patient's physical or m	e sclerosis. itment. ities as defi ysical or me	ned by th sntal heal	le Americ. th.	ans with Di	sabilities

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		Table 2. Variation among State Me	dical Marijuana Laws.	
State	Year Passed	Limits on Quantity (dried marijuana and plants)	State Registration Protects "Qualifying" Patients from Arrest and Prosecution	Dispensaries Established by State Law
California	1996	"Quantity should be reasonably related to patient's current medical needs" (for nonregistered pa- tients); 8 oz and no more than 6 mature or 12 immature plants (for registered patients)*	Yes	Yes
Alaska	1998	1 oz and 6 plants — no more than 3 mature	No†	No
Oregon	1998	24 oz and up to 6 mature plants and 18 seedlings	Yes	No
Washington	1998	24 oz and 15 plants	Law does not require, and state has not established, a registry	No
Maine	1999	2.5 oz and 6 plants	Yes‡∬	Allows establishment of non- profit dispensaries
Colorado	2000	2 oz and 6 plants — no more than 3 mature	Yes	No
Hawaii	2000	Qualifying patients can have "adequate supply" — defined as no more than 3 mature plants, 4 imma- ture plants, and 1 usable oz from each mature plant	No†	No
Nevada	2000	1 oz and no more than 3 mature and 4 immature plants	Yes	No
Montana	2004	1 oz and no more than 6 plants	Yes	No
Vermont	2004	2 oz and no more than 2 mature and 7 immature plants	Yes	No
Rhode Island	2006	2.5 oz and no more than 12 plants	Yes	Allows creation of compassion centers that can dispense marijuana
New Mexico	2007	6 oz, 4 mature plants, and 12 seedlings	Yes	No
Michigan	2008	2.5 oz and 12 plants	Yes	No
New Jersey	2010	2 oz	No†‡	Allows creation of alternative treatment centers that can dispense marijuana

\* These limits were established in legislation passed in 2004.

† Registered patients are not protected from arrest but may assert an affirmative defense of medical use of marijuana.

‡ A registration program has not yet been established.

 $m \mathring{j}$  A 2009 amendment required the state to establish a registry.

In states debating new legislation, policymakers are grappling with questions that only scientific research can answer: For what conditions does marijuana provide medicinal benefits? Are there equally effective alternatives? What are the appropriate doses for various conditions? How can states ensure quality and purity?

Although state laws represent a political response to patients seeking relief from debilitating symptoms, they are inadequate to advance effective treatment. Medical experts emphasize the need to reclassify marijuana as a Schedule II drug to facilitate rigorous scientific evaluation of the potential therapeutic benefits of cannabinoids and to determine the optimal dose and delivery route for conditions in which efficacy is established.<sup>2</sup> This research could provide the basis for regulation by the Food and Drug Administration. Current roadblocks to conducting clinical trials, however, make this more rational route of approval unlikely and perpetuate the development of state laws that lack consistency or consensus on basic features of an evidence-based therapeutic program.

Reliance on state laws as the basis for access to medical mari-

juana also leaves patients and physicians in a precarious legal position. Although the current Justice Department may not prosecute patients if they use marijuana in a manner consistent with their states' laws, the federal law remains unchanged, and future administrations could return to previous enforcement practices.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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## Let's Move — Childhood Obesity Prevention from Pregnancy and Infancy Onward

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irst Lady Michelle Obama un-Fveiled her "Let's Move" campaign against childhood obesity on February 9, 2010. The program's main antiobesity strategies are empowering parents and consumers by revamping the nutritional labeling of products by the U.S. Department of Agriculture (USDA), improving the nutritional standards of the National School Lunch Program, increasing children's opportunities for physical activity, and improving access to high-quality foods in all U.S. communities (www.letsmove.gov).

This innovative multifactorial approach has potential for altering the course of the childhood obesity crisis - changing our country's approach to eating, nutrition, and physical activity by simultaneously targeting individuals, neighborhoods, and larger communities. Current data on obesity in school-age children are sobering. Almost one third of U.S. children over 2 years of age are already overweight or obese, according to the 2007-2008 National Health and Nutrition Examination Survey (see graph), and among low-income children 2 to 5 years of age who are enrolled in federally funded health programs, the proportions range as high as 39%



An interactive ( map is available t at NEIM.org a

(see map, and the interactive map available with the full text of this article at NEJM.org). But systematic reviews indicate that, at best, behavioral and nutrition interventions in schools or within the home have limited success in preventing weight gain in children.1 At as early as 3 years of age, obese children have elevated levels of inflammatory markers that have been linked to heart disease that is manifested later in life.<sup>2</sup> To be a truly comprehensive and successful program, then, the Let's Move campaign must stimulate prevention efforts targeting the youngest Americans - those under 2 years of age and preschoolers. Indeed, prevention must start as early as possible, since school-age children already have an unacceptably high prevalence of obesity and associated medical conditions.

Factors associated with increased risk for overweight or obesity in infancy and early childhood include excessive maternal weight gain or smoking during gestation, shorter-than-recommended duration of breast-feeding, and suboptimal amounts of sleep during infancy. Such exposures during early development program a person's long-term regulation of energy balance and may have epigenetic effects. These exposures probably influence the development of hypothalamic circuits that regulate body weight,

as well as endocrine pancreatic function, changes in the proportion of lean versus fat body mass, and other cycles of metabolic programming.<sup>3</sup>

Interventions designed to reduce excessive weight gain and smoking during pregnancy, to increase the duration of breastfeeding, and to increase sleep duration during infancy could target U.S. children before they became overweight or obese, intervening in the cycle of metabolic programming that can be influenced by these early-life exposures. We believe that these types of interventions are crucial to include in a comprehensive obesity-prevention effort, since they affect a child's lifetime risk of obesity.

Studies have shown that early interventions can potentially prevent the development of obesity in school-age children, along with associated health conditions. Wrotniak and colleagues found that the risk of having a child who was overweight at 7 years of age was 48% higher among women who gained more weight during pregnancy than recommended in the Institute of Medicine (IOM) guidelines than among women whose weight gain was within the recommended range.4 The World Health Organization has affirmed that the long-term benefits of breast-feeding include

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